REMARKS

Claims 1-28 are pending in this application. Claims 22-28 have been newly added.

Claims 1, 11 and 17 have been amended for the sole reason of advancing prosecution. Applicants, by amending any claims herein, make no admission as to the validity of any rejection made by the Examiner against any claims.

Newly added claims 22-26 are directed to the catamenial tampon of claims 12-16, respectively, and recite "wherein the formulation is deposited on a strip." Support for newly added claims 22-26 can be found, for example, at page 3, lines 17-19 of the specification as originally filed, which recites "The formulation may be placed directly on the tampon, or indirectly, e.g. on a strip...." *See also*, the Examples at page 6, lines 22-27. No new matter has been added.

New claim 27 is directed to "A method for reducing the pH in a menstruating vagina to below pH 5.5 comprising inserting into the vagina, a catamenial tampon comprising the formulation of claim 1." New claim 28 is dependent on new claim 27 and further recites "wherein after inserting, pH in the menstruating vagina is reduced to below pH 5.5." Support for new claims 27-28 appears throughout the specification and claims as originally filed, at for example, at page 6, line 5.

Claims 1, 11 and 17 have been amended to recite "30-100% by weight of glycolide" in place of "3-100% by weight of glycolide." Support for amended claims 1, 11 and 17 can be found, for example, at page 5, lines 3-5, of the specification as originally filed, which recites "The glycolide comprises 3-100% of the formulation, with a preferred lower boundary of 30%...." No new matter has been added.

In view of the following, further and favorable consideration is respectfully requested.

I. At page 2 of the Official Action, claims 1-3, 5-8, 11 and 17 have been rejected under 35 USC § 102(b) as being anticipated by WO 2000/059556 (Besemer et al.).

The Examiner asserts that Besemer et al. anticipates each element of claims 1-3, 5-8, 11 and 17.

In view of the remarks herein, this rejection is respectfully traversed.

The test for anticipation is whether each and every element as set forth is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California,* 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP § 2131. The identical invention must be shown in as complete detail as is contained in the claim. R*ichardson v. Suzuki Motor Co.,* 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131. The elements must also be arranged as required by the claim. *In re Bond,* 15 USPQ2d 1566 (Fed. Cir. 1990).

As discussed, present claim 1 is directed to a formulation effective in reducing the pH in a menstruating vagina or in a tampon inserted therein to below pH 5.5 comprising: (a) 30-100% by weight of glycolide; (b) optionally, 97-15% by weight of a solid organic acid; and (c) optionally, 5-30% of a wetting agent. Claims 2-3 and 5-8 depend, directly or indirectly, from claim 1.

Claim 11 is directed to a formulation effective in reducing the pH in a menstruating vagina or in a tampon inserted therein to below pH 5.5 comprising: (a) 30-100% by weight of

glycolide; (b) optionally, 3-97% by weight of lactide; (c) optionally, 97-15% by weight of a solid organic acid; and (d) optionally, 5-30% of a wetting agent.

Claim 17 is directed to a formulation effective in reducing the pH in a menstruating vagina or in a tampon inserted therein to below pH 5.5, consisting of: (a) 30-100% by weight of glycolide; (b) optionally, 3-97% by weight of lactide; (c) optionally, 97-15% by weight of a solid organic acid; and (d) optionally, 5-30% of a wetting agent.

All of the pending claims recite "30-100% by weight of glycolide."

At the onset, Applicants note that Besemer confuses two terms – "lactide" and "lactone." In paragraph [0005] Besemer states: "*Lactides include cyclic esters of hydroxyl acids, especially α-hydroxy acids such as glycolic acid and lactic acid.*" This is incorrect. Lactides are cyclic esters of lactic acid only, while glycolides (which are the subject of the present application) are cyclic esters of glycolic acid only. Both lactide and glycolide are types of lactones.

In contrast to the presently claimed subject matter, Besemer et al. is directed to a superabsorbent material for controlling odor and bacterial growth which comprises a non-acidic, alkali-neutralizing compound selected from acid anhydrides, lactides, lactones and hydrolysable esters. *See*, for example, paragraphs 1-2 and 8 of Besemer et al. One example of an alkali-neutralizing compound described in Besemer et al. is glycolide. *See Id.* at paragraphs 4, 5 and 14, as well as claim 3. Besemer et al. do not teach a formulation comprising "30-100% by weight of glycolide" as required by all of the pending claims. Rather, Besemer et al. describes that the amount of neutralizing agent can be 1-20% by weight, preferably 3-12% by weight (*see* paragraph [0006] and claim 4).

In view of the foregoing, it is submitted that Besemer et al. does not teach, either expressly or inherently, each and every element of the presently claimed subject matter, as required for anticipation under 35 USC § 102 (b). Accordingly, the Examiner is respectfully requested to withdraw this rejection of claims1-3, 5-8, 11 and 17.

II. At page 2 of the Official Action, claims 1-21, have been rejected under 35 USC §103(a) as being unpatentable over Besemer et al. in view of Kluger et al. (of record) and in further view of Sinclair et al. (US Patent No. 5,444,113).

The Examiner asserts that Besemer et al. "very clearly teaches of sanitary products that contain lactide ...by incorporating lactide into the product the pH is lowered quickly...Kluger et al teach of a formulation effective in reducing the pH in a menstruating vagina or in a tampon inserted therein to below pH 5.5. Sinclair et al. teach polymers dioxaneones such as lactide and glycolide. Glycolide and lactide can be used interchangeably in sanitary products and provide the same effect since both of them are used to reduce the pH. WO 0059556 anticipates the claimed invention. Accordingly, the above mentioned references,... in combination render the claimed invention obvious."

In view of the remarks herein, this rejection is respectfully traversed.

To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court held in *KSR International Co. v. Teleflex Inc. et al.*, 550 U.S. 398 (2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to

determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (*KSR*, *supra*) Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

Recently, the Federal Circuit in *Takeda Chemical Industries v. Alphapharm*, No. 06-1329, slip op. (Fed. Cir. June 28, 2007), has **applied the TSM test after *KSR***. The Appellant in this declaratory judgment action argued that the claimed chemical compound was an obvious modification of a previously known compound—the modification requiring the substitution of a homolog in a different ring position. (*Id.* at 5.) The Federal Circuit rejected this, holding that "in cases involving new chemical compounds, it remains necessary to identify some reasons that would have led a chemist to modify a known compound in a particular manner to establish *prima facie* obviousness of a new claimed compound." (*Id.* at 10.) Notably, the Court also rejected the Appellant's "obvious to try" argument, as the Appellant failed to demonstrate that one of ordinary skill would have chosen the prior art compound to modify from the millions of possibilities. (*Id.* at 15.)

It is submitted that a *prima facie* case of obviousness has not been established because there is no motivation to combine Besemer et al., Kluger et al. and Sinclair et al., and because, whether taken alone or in combination, Besemer et al., Kluger et al. and Sinclair et al. do not teach or suggest all the limitations of the present claims as required by *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

From the outset, Applicants note that there is no motivation to combine Besemer et al., Kluger et al. and Sinclair et al. because each of the cited references are directed to entirely different subject matter. In this regard, none of the cited references describe subject matter useful for the same purpose. Specifically, Applicants note that Besemer et al. is directed to improving odor control of urine in diapers and sanitary napkins. In contrast, Kluger et al. describe reducing the pH in a menstruating vagina or in a tampon inserted therein. On the other hand Sinclair et al. describe the production of commercial products which are easily degraded. Applicants respectfully submit that a person of ordinary skill in the art would not be motivated to combine the teachings gleaned from any of: a reference describing diapers; a reference describing the reduction of the pH of a vagina or tampon inserted in a vagina; and a reference directed to the production of commercial products. Accordingly, Applicants submit that there is no motivation to combine the cited reference.

Assuming *arguendo* that the combination of references is proper, none of Besemer et al., Kluger et al. and Sinclair et al. teach or suggest all the limitations of the claims as required by *In re Wilson*. Specifically, whether taken alone or in combination, none of Besemer et al., Kluger et al. and Sinclair et al. teach or suggest a "formulation ***effective in reducing the pH in a menstruating vagina or in a tampon inserted therein*** to below pH

5.5" either comprising or consisting of glycolide, as recited by each of the pending independent claims.

As discussed, present claim 1 is directed to a formulation effective in reducing the pH in a menstruating vagina or in a tampon inserted therein to below pH 5.5 comprising: (a) 30-100% by weight of glycolide; (b) optionally, 97-15% by weight of a solid organic acid; and (c) optionally, 5-30% of a wetting agent. Claims 2-10, 12-15, 18-25 and 27-28 depend, directly or indirectly, from claim 1.

Claim 11 is directed to a formulation effective in reducing the pH in a menstruating vagina or in a tampon inserted therein to below pH 5.5 comprising: (a) 30-100% by weight of glycolide; (b) optionally, 3-97% by weight of lactide; (c) optionally, 97-15% by weight of a solid organic acid; and (d) optionally, 5-30% of a wetting agent. Claims 16 and 26 depend from claim 11.

Claim 17 is directed to a formulation effective in reducing the pH in a menstruating vagina or in a tampon inserted therein to below pH 5.5, consisting of: (a) 30-100% by weight of glycolide; (b) optionally, 3-97% by weight of lactide; (c) optionally, 97-15% by weight of a solid organic acid; and (d) optionally, 5-30% of a wetting agent.

The Examiner appears to equate the superabsorbent material of Besemer et al. with an absorbent material suitable for use in a tampon. Kluger et al. is cited for teaching a formulation effective in reducing the pH in a menstruating vagina or in a tampon inserted therein to below pH 5.5, including an organic acid polymer (i.e., lactide), a solid organic acid and a wetting agent. The Examiner cites Sinclair et al. as teaching dioxanediones which term "is sometimes used to refer specifically to glycolide" and "can be also employed in the general sense to indicate a class of compounds."

Applicants politely emphasize that the present subject matter is directed to a formulation comprising ***glycolide***, and ***not*** a polymer thereof.

The Examiner states on page 3 of the Official Action with regard to Besemer et al., that "WO 0059556 very clearly teaches of sanitary products that contain ***lactide*** and as shown in WO 0059556 by incorporating ***lactide*** into the product the pH is lowered quickly" (emphasis added). However, the present claims recite a formulation comprising ***glycolide***. The Examiner further states that "Glycolide and lactide can be used interchangably...."

Sinclair et al. describe only that dioxanediones, "is sometimes used to refer specifically to glycolide," "can be also employed in the general sense to indicate a class of compounds." It appears that the Examiner is asserting that because lactide and glycolide could both be considered a dioxanone (are both from the same class of compounds), they are equivalent and interchangeable. The Examiner goes on to state that "glycolide can be used in combination with lactide or separately in a formulation without any physiological effect to the composition." *See* page 7 of the June 12, 2008 Official Action.

Applicants question the Examiners basis for such a statement and request that the Examiner cite authority that would establish that glycolide and lactide are interchangeable, and that glycolide can be used in combination with lactide or separately in a formulation without any physiological effect to the composition, should this rejection be maintained.

Sinclair et al. do not establish that glycolide and lactide are interchangeable. Rather, Sinclair et al. simply assert that lactide and glycolide could both be considered a dioxanone. Further, the data set forth in the Examples of the present specification clearly establishes that lactide and glycolide ***are not interchangeable,*** and that the use of glycolide exhibits unexpectedly superior results over the use of lactide. Please *see* the

below discussion of the Examples set forth in the specification.

Applicants again assert that ***glycolide and lactide are not interchangeable***. Rather, they are ***different*** cyclic esters having ***different*** chemical properties.

Glycolide is a completely different molecule than lactide. Glycolide has a different molecular structure and different properties than lactide. Glycolide is a cyclic dimer of two glycolic acid molecules, while lactide is a cyclic dimer of two lactic acid molecules. The main difference between lactide and glycolide, is that ***glycolide is hydrophilic*** and ***lactide is hydrophobic***. This is due to the absence, in glycolide, of the two pendant methyl groups which are present in lactide. Thus, glycolide undergoes hydrolysis (and converts into two glycolic acid molecules) much more efficiently and quickly than lactide, for example, during tampon usage. This well-know difference in properties of lactide and glycolide is used to tailor the degradation kinetics of many known artificial implants and medical devices, the most familiar of which are the degradable sutures. Such sutures can be made of copolymers synthesized from lactide (hydrophobic) and glycolide (hydrophilic), the ratio between the two components in the polymer dictates the degradation rate of the polymer, which should be approximately at the rate of tissue healing. In view of the foregoing, it is clear that glycolide and lactide have ***significantly different properties*** and are thus, ***not*** interchangeable.

Glycolide is a cyclic dimer of glycolic acid. *See* the Dictionary of Organic Compounds, 1,4-dioxane-2,5-dione; Names, Synonyms, and Structures of Organic Compounds, page 488; and SciFinder Scholar, 1,4-dioxane-2,5-dione. A copy of each of which was submitted with the Amendment and Response filed on March 20, 2008. *See also* www.sigma-aldrich.com "glycolide" (printout submitted with the Amendment and Response filed on March 20, 2008) and www.bio-invigor.com "GLY-S-001-1" (printout submitted with

the Amendment and Response filed on March 20, 2008). Further, U.S. Patent Nos. 3,457,280 and 3,435,008 (submitted with the Amendment and Response filed on March 20, 2008) both describe that two molecules of glycolic acid "may condense with the elimination of two molecules of water to produce glycolide, a six-membered ring of the formula $C_4H_4O_4$...." U.S. Patent No. 5,374,743 describes at col. 1, lines 9-11, "The monomer used is lactide or glycolide which are cyclic dimmers of lactic acid or glycolic acid and which are prepared from lactic acid or glycolic acid." *See also* U.S. Patent Nos. 6,891,048 and 7,235,673 submitted with the Amendment and Response filed on March 20, 2008.

In addition, lactide is a cyclic dimer of lactic acid. *See* http://en.wikipedia.org/wiki/Lactide.

These differences in properties between lactide and glycolide result in surprising advantages using glycolide rather than lactide to reduce pH, as supported by the results described in the Examples set forth in the present specification, and described below:

1. **Fig. 1** shows "surprisingly that the degradation process of glycolide is significantly faster than that of lactide." (*see* page 6, lines 16-17).
2. In the experiment of **Fig. 2** in which the glycolide and lactide are deposited on strips, "Still, the relative difference between the two compounds is maintained" (*see* page 6, line 31 – page 7 line 1).
3. In the experiment of **Fig. 4**, it was shown that "one of the advantages in using glycolide is the reduced necessity of using a wetting agent in terms of improving degradation and release kinetics," and "It thus may be seen that by replacing lactide with glycolide, the necessity of adding an organic acid

and/or wetting agent is diminished or eliminated." (*see* page 7, line 29 to page 8, line 3).

4. "The results presented in **Figure 6**, indicate that the combination of glycolide and citric acid is ***consistently more efficacious*** than the lactide – citric acid combination, again indicating that without the presence of a wetting agent, glycolide degrades quicker than lactide." (*see* page 8, lines 11-14)

Thus, the specification provides ample proof of the superiority of glycolide over lactide, and further evidences that ***glycolide and lactide are NOT interchangeable***. This feature is ***not*** taught or suggested by ***any of the cited references***, taken alone or in combination. Again, should this rejection be maintained, the Examiner is requested to expressly address this argument as well as the data set forth in the Examples of the present specification.

As discussed above, Besemer et al. confuse lactide with glycolide and do not teach the advantage of using glycolide in place of lactide. *See* above, with regard to the rejection of the claims under 35 USC § 102. Besemer et al. is directed to hygienic superabsorbent products used outside the body, such as diapers and sanitary napkins (*see* [0001] and examples). The Examiner appears to be equating the superabsorbent material of Besemer et al. with an absorbent material suitable for use in a tampon. Applicants again assert that superabsorbent materials are ***contraindicated*** for use in the vagina or in tampons.

More specifically, the Examiner states on page 3 of the Official Action that "as Applicant indicates superabsorbent materials may ...promote ...not factual data and cannot be relied on." Applicants note that in an article from the Food and Drug Administration (FDA Consumer magazine March-April 2000) on Tampon Safety, it is

reported that Proctor & Gamble as well as competing manufactures voluntarily ***withdrew tampons containing superabsorbent materials from the market in 1980***. *See* http://www.fda.gov/fdac/features/2000/200_tss.html. As a result, ***the number of TSS cases plummeted.***

Thus, because Besemer et al. ***require*** superabsorbent materials, Besemer et al. cannot be construed to suggest a tampon or formulation for use in a tampon. In fact, Besemer et al. ***teach away*** from the presently claimed subject matter.

Besemer et al. is discussed above with regard to the rejection under 35 USC § 102(b). As discussed, Besemer et al. do not teach or suggest a "formulation ***effective in reducing the pH in a menstruating vagina or in a tampon inserted therein*** to below pH 5.5" either comprising or consisting of glycolide, as recited by each of the pending independent claims. In addition, as discussed, Besemer et al. do not teach a formulation comprising 30-100% by weight glycolide, as presently claimed. Further, Besemer et al. require superabsorbent materials and do not teach or suggest a tampon or a formulation for insertion into the body in view of the FDA article cited above.

Kluger et al. do not remedy the deficiencies of Besemer et al. Kluger et al. do not teach or suggest glycolide at all, let alone the advantages of using glycolide over lactide. In fact, the term "glycolide" ***does not appear at all*** in Kluger et al.

One of ordinary skill in the art would have no reason to use glycolide for the solid organic acid polymer based on the disclosure of Kluger et al. Accordingly, like Besemer et al., Kluger et al. do not teach or suggest a "formulation ***effective in reducing the pH in a menstruating vagina or in a tampon inserted therein*** to below pH 5.5" either comprising

or consisting of glycolide. Therefore, whether alone or in combination, none of the cited references teach or suggest the presently claimed subject matter.

Sinclair et al. do not remedy the deficiencies of Besemer et al. and Kluger et al. Sinclair et al. is directed to products made of degradable materials which include a hydrolytically degradable polymer. *See* Sinclair et al. at the Abstract. However, like Besemer et al. and Kluger, Sinclair et al. also do not teach or suggest a "formulation ***effective in reducing the pH in a menstruating vagina or in a tampon inserted therein*** to below pH 5.5" either comprising or consisting of glycolide, as presently claimed. Sinclair et al. describes degradable materials are useful for the production of commercial products which are easily degraded, thus contributing to improving the environment. *See* Sinclair et al. at col. 4, lines 35-49). The disclosed ***polymer*** is characterized as comprising ***REPEATING monomer or comonomer units*** derived from, for example, glycolide. *See* Sinclair et al. at col. 7, lines 33-50. However, as indicated above, the presently claimed subject matter recites ***the monomer glycolide, and not polymers of glycolide***. Therefore, whether taken alone or in combination, none of the cited references teach or suggest a "formulation effective in reducing the pH in a menstruating vagina or in a tampon inserted therein to below pH 5.5" either comprising or consisting of glycolide, as presently claimed.

In view of the foregoing, it is submitted nothing in Besemer et al., Kluger et al. and Sinclair et al., taken alone or in combination, renders the presently claimed subject matter obvious within the meaning of 35 U.S.C. § 103(a). Therefore, Applicants respectfully submit a *prima facie* case of obviousness has not been established. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

III. Claims 22-28:

Applicants respectfully submit that newly added claims 22-28 are also novel and non-obvious. In this regard, Applicants submit that claims 22-28 are novel and non-obvious for at least the reason that they depend from claim 1, 11 or 17, which as discussed above are novel and non-obvious.

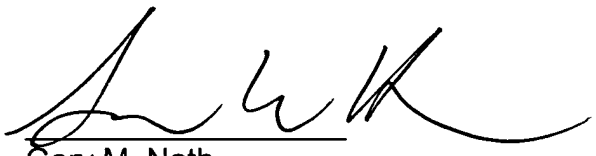
CONCLUSION

Applicants assert that the claims are in condition for immediate allowance and early notice to that effect is earnestly solicited. Should the Examiner deem that any further action by Applicants' undersigned representative is desirable and/or necessary, the Examiner is invited to telephone the undersigned at the number set forth below.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

THE NATH LAW GROUP



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